SHORT COMMUNICATION

Provisional stenting technique in the left main bifurcation setting: Computational fluid dynamics and optical coherence tomography pilot study in humans

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INTRODUCTION

Due to complex morphology of bifurcation lesions, they are associated with a higher number of adverse events following stent implantation, such as stent thrombosis and in-stent restenosis [1]. Because of the differences in diameter between the proximal and distal parts of the vessel and the side branch (SB), appropriate implantation techniques, such as proximal optimization (POT) and frequently SB optimization, are necessary to achieve optimal procedural results. In left main (LM) stenting, the provisional, single-stent strategy is associated with outcomes comparable to the more complicated double-stent strategy [2]. Previous meta-analyses of randomized trials demonstrated similar clinical outcomes regardless of SB optimization with the kissing-balloon inflation (KBI) technique [3]. However, up to date no large randomized trials focusing on the impact of final POT after KBI were performed. We previously conducted benchtop tests that demonstrated significant differences in flow disturbances at SB ostia with and without KBI optimization in the LM setting [4]. Therefore, in this pilot human study, we aimed to evaluate the impact of KBI followed by final POT in LM interventions based on optical coherence tomography (OCT) images and computational fluid dynamics (CFD) reconstructions.

METHODS

This pilot study was conducted in the Division of Cardiology and Structural Heart Diseases at the Medical University of Silesia in Katowice between February and July 2021. Patients' clinical data are provided in the Supplementary material. The study received approval from the Bioethical Committee and adhered to the Declaration of Helsinki. All patients underwent surgery using a provisional stenting technique according to recommendations of the European Society of Cardiology, with a single stent (Xience Sierra, Abbott, Santa Clara, CA, US) positioned from the LM to the left anterior descending artery. The following steps were performed in each patient: predilatation, stent implantation, POT, KBI, and final POT. All balloon inflations were carried out using non-compliant balloons sized according to the distal segment of the target vessel. OCT images were obtained before stenting and after each stage of the procedure using the ILUMEN OPTIS system (Abbott, US). Subsequently, all OCT images were analyzed by a qualified medical staff at 1 mm intervals. Malapposition was defined as a distance between the strut blooming and lumen contour of more than 81 µm. Floating struts were described as all struts observed in the opening angle of the SB. Furthermore, to understand the effects of overhanging struts at the boundary intersection between the main and side branches, CFD analysis was performed. Two-dimensional models were created from the cross-sectional OCT pullbacks using Solidworks. The models underwent simulations using fluid computational software (Fluent, ANSYS). For analysis, a region of interest was created based on the SB diameter intersecting the main branch (MB), encompassing any overhanging struts, in each analysis model [5]. Parameters of interest analyzed in these regions included maximum shear rate (SR) and area of high SR.

Statistical analysis

IBM SPSS Statistics 29 (version 29; IBM, Armonk, NY, US) was used to perform the statistical analysis for exploratory purposes. Results were shown as a mean value (range and standard deviation). The values represent a normal distribution; therefore, they were analyzed with parametric tests (one-way analysis of variance for dependent samples). The differences were considered meaningful if a *P*-value was <0.05. If the *P*-value was in the range between 0.05 and 0.10, the differences were considered a statistical tendency.

RESULTS AND DISCUSSIONS

In this pilot study, we aimed to evaluate the effects of POT, KBI, and final POT on morphometric OCT parameters and flow disturbances in the SB ostium using CFD analysis in the LM setting. Because of their morphological complexity, bifurcation lesions, especially in the LM region, are prone to a higher number of adverse events [1]. In our study, OCT analysis demonstrated a positive trend in the LM minimal lumen area, starting from 4.99 mm^2 (3.58–6.11; SD, 1.29) before stent implantation to 8.76 mm^2 (5.88–12.06; SD, 3.11) after POT, 8.78 mm^2 (6.84–11.6; SD, 2.51) after KBI, and 10.29 mm^2 (8.76–12.36; SD, 1.86) after final POT; *P* = 0.064. However, after performing the correction for multiple comparisons, none of the compared pairs differed significantly from each other. We observed a significant difference in the LM minimal stent area (MSA) after each stage, with 8.88 mm^2 (6.83–12.52; SD, 3.16) after POT, 9.24 mm^2 (7.11–13.0; SD, 3.27) after KBI, and 11.42 mm^2 (9.52–13.85; SD, 2.21) after final POT; *P* <0.05, with positive tendency between POT and KBI (*P* = 0.093). This is an important finding since a smaller post-implantation minimal lumen area and minimal stent area (indicating stent under-expansion) were found to be independent predictors of stent failure, including ST and in-stent restenosis [6]. The number of malapposed struts registered in each frame in the region of interest decreased numerically after each stage, with no statistical significance: 4.67 (0–11; SD, 5.69) after POT, 4 (0–10; SD, 5.29) after KBI, and 2.33 (0–5; SD, 2.52) after final POT; *P* = 0.35. The number of floating struts in the SB region decreased significantly: 39 (18–55; SD, 19) after POT, 28.33 (12–41; SD, 14.84) after KBI, and 26.67 (9–40; SD, 15.95) after final POT, *P* <0.05. We also observed a positive trend in floating struts between POT and final-POT (*P* = 0.06). Previously published bench-test studies demonstrated a correlation between struts protruding into the SB ostium and increased thrombogenicity [4].

The SR was defined as the local gradient in velocity between two surfaces that contain the fluid. Blood flow disruption and the extension of high shear rate regions may be caused by the presence of struts in the SB ostia.

In our study, CFD analysis showed a significant difference in the number of maximum shear rates at SB ostia after stent implantation: 390.07 s^{-1} (115.5–616.7; SD, 254.01), subsequent POT: 1522.1 s^{-1} (450.5–3049.6; SD, 1358.2) and KBI: 2370.77 s^{-1} (1489.5–3843.3; SD, 1283.47) with a reduction after final POT: 454.1 s^{-1} (356.4–518.6; SD, 86.05), *P* <0.05, with a positive tendency between POT and KBI (*P* = 0.08). In areas with SR >1000 s^{-1}, we did not observe a significant difference with 0 mm^2 (0–0; SD, 0) at baseline, 0.02 mm^2 (0–0.07; SD, 0.04) following implantation with subsequent POT, 0.02 mm^2 (0.004–0.066; SD, 0.04) after KBI, and 0 mm^2 (0–0; SD, 0) after final POT; *P* = 0.39. Representative images of OCT and CFD are presented in Figure 1. In the distal LM lesions, POT plays a crucial role in the MB optimization proximally to the SB and is mandatory to improve stent expansion and strut apposition [9]. Also, it allows adjusting the stent shape to the fractal geometry of the vessel and correcting the flow dynamics. However, despite the theoretical reduction of floating struts at the SB ostia following KBI, its clinical impact is still debated. Nevertheless, it is important to emphasize that KBI may be responsible for ellipsoid stent distortion of the proximal MB and its excessive overexpansion, which might be associated with higher risk of MB-related adverse events [10]. Finally, data from a randomized trial comparing provisional stenting with or without KBI did not demonstrate any improvements in clinical outcomes for the KBI strategy [3].

A few limitations are important to highlight. First, the number of patients analyzed in this preliminary study was small. Additionally, our study assessed only one DES platform, thus the results might differ with other devices.

In conclusion, based on these preliminary results, we demonstrated that performing KBI without following stent optimization may disrupt stent geometry unless it is followed by final POT, which is associated with numerical improvements of OCT morphometric parameters as well as a reduction of floating struts at SB ostia and the area of high shear rate in CFD analysis. This shows the potential of KBI followed by final POT in further reducing the number of adverse events in patients with distal LM lesions. Nevertheless, larger studies evaluating the impact of SB optimization are crucial to further explore these preliminary findings.

Article information

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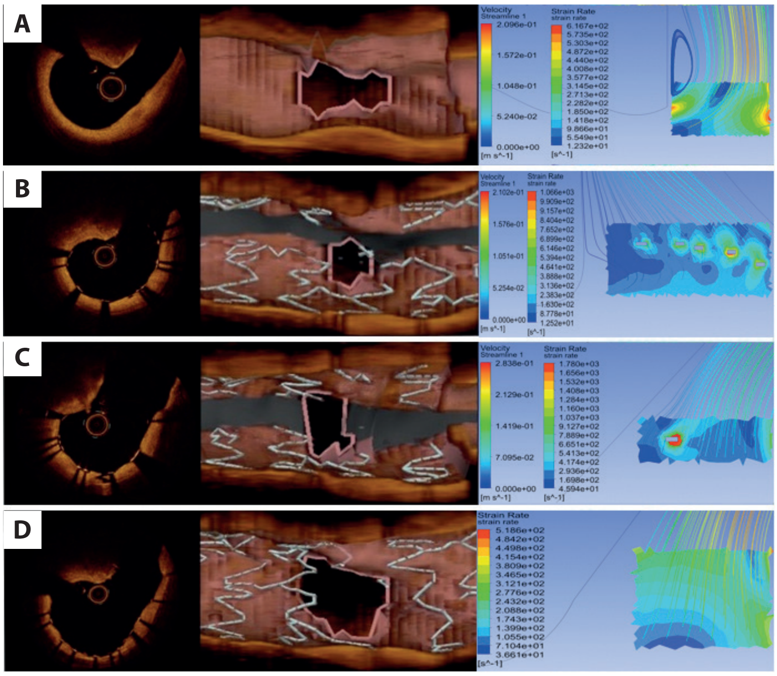

Figure 1. Representative images. **A.** Before stent implantation: left OCT 2D, middle OCT 3D, right CFD. **B.** After POT: left OCT 2D, middle OCT 3D, right CFD. **C.** After KBI: left OCT 2D, middle OCT 3D, right CFD. **D.** After final POT: left OCT 2D, middle OCT 3D, right CFD

Abbreviations: CFD, computational fluid dynamics; KBI, kissing-balloon inflation; OCT, optical coherence tomography; POT, proximal optimization

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